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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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PATENT DEPARTMENT
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EXAMINER

RAO, MANJUNATH N

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/742,690	DAVIS ET AL.
	Examiner Manjunath N. Rao, Ph.D.	Art Unit 1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 20 June 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-3,5,8,10,12 and 14-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-3,5,8,10,12 and 14-17 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) Interview Summary (PTO-413) Paper No(s) _____.
5) Notice of Informal Patent Application (PTO-152)
6) Other:

DETAILED ACTION

Claims 1-3, 5, 8, 10, 12, 14-17 are currently pending and are present for examination.

Claims 1-3, 5, 8, 10, 12, 14, 17 are now under consideration. Claims 15-16 remain withdrawn from consideration as being drawn to non-elected group.

Applicants' amendments and arguments filed on 5-13-03 and 6-20-03, paper No. 20 and 23, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 5, 8, 10, 12, 14, 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Shoseyov et al. (US 5,719,044, 2-17-1998). This rejection is based upon the public availability of a printed publication or that the invention was already patented by others. Claims 1-2, 5, 8, 10, 12, 14, 17 of the instant application are drawn to a fusion protein comprising CBD and a domain having a high binding domain for another ligand (claim 1) with a binding equilibrium constant of less than 10^{-4} M, and wherein the high binding domain is an antibody or a fragment of an antibody directed at a benefit agent, a fabric or a specific part of a fabric or micro-particles of unknown chemical make-up, wherein the CBD is obtained from a variety of fungi or bacteria

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including *Clostridium* (claim 2), wherein the high binding domain antibody is heavy chain antibody as found in Camelidae (claim 5), wherein the high binding affinity domain (antibody) is directed to a benefit agent selected from a group as recited in claim 8, wherein the antibody is directed to the fabric (claim 14), polyester, polyester/cotton or wool (claim 10), wherein the CBD and the high binding domains are linked by means of a linker consisting of 2-5 or 2-15 amino acids (claims 12 and 17). Shoseyov et al. disclose an identical fusion protein comprising a CBD obtained from *Clostridium* and a high affinity binding domain, wherein the high binding domain is an antibody of heavy chain type directed to proteins and hormones (see column 4, lines 45-58 or claims 4-5 and figure 12), and wherein the CBD and the high affinity binding domain are linked by means of (cleavage site) linker (see column 5 lines 24-33). Thus Shoseyov et al. anticipate claims 1-2, 5, 8, 10, 12, 14, 17 of this application as written.

Applicants may argue that the above reference does not anticipate every limitation of the claimed invention. Applicants may argue that the reference does not disclose that binding equilibrium constant for the high affinity binding domain with its ligand is lower than 10^{-4} M, or that the high binding affinity binding domain is not directed to a benefit agent, or polyester, polyester/cotton, wool etc. or that the antibody is not of the heavy chain as found in Camelidae and that the linker region does not consist of either 2-5 or 2-15 amino acids. However, such arguments would not be persuasive to overcome the rejection because as the inventions are so closely related Examiner takes the position that the fusion protein in the reference has all the features of the fusion protein claimed in the instant invention even though such limitation are not clearly mentioned in the reference. Since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on the applicant

to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

In response to the previous Office action, applicants argue that Shoseyov et al. differs from the present claims in that it does not teach or suggest any chemical equilibrium constant or equilibrium constant to be lower than $10^{-4}M$ for the high affinity binding antibody domain of the fusion protein. Examiner respectfully disagrees. Shoseyov et al. disclose an invention comprising a fusion protein which comprises a high affinity binding antibody domain. Based on this Examiner has used the inherency argument that irrespective of the disclosure by Shoseyov et al., the equilibrium constant for the high affinity binding antibody domain, the reference anticipates instant invention as binding affinity constant for an antibody antigen complex is inherent. Applicants also argue that if the Examiner is relying on his own knowledge of the binding constants of Shoseyov et al. an affidavit is required. Examiner respectfully disagrees with such an argument and sees no need to provide to provide any such affidavit. This is because Examiner is basing his argument on inherency. The binding constant for a complex between an antibody and an antigen is inherent. Therefore, while Shoseyov et al. may not provide a numerical value to the binding of the antibody of their fusion protein, such characteristic is inherently existing in that invention. As stated by applicants themselves, the reference necessarily results in the applicants invention based on inherency. Therefor for all the above reasons Examiner continues to maintain the above rejection as well as the obviousness rejection that follows.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shoseyov et al. as applied to claims 1-2, 5, 8, 10, 12, 14, 17 above, and further in view of Linder et al. (PNAS, 1996, Vol. 93:12251-55). Claim 3 of this application is drawn to a fusion protein comprising CBD and a domain having high binding affinity for another ligand (claim 1), wherein the CBD is obtained from *T.reesei*, wherein the high binding affinity domain is an antibody or a antibody fragment such as a Heavy Chain antibody as found in Camelidae, wherein the domain having a high binding affinity is directed to a “benefit agent” selected from a group as in claim 8, or at the fabric or at polyester etc. or at a specific part of a fabric or at micro-particles loaded with a benefit agent wherein the CBD is connected to the domain by an amino acid linker of 2-15 or 2-5 amino acids.

The reference of Shoseyov et al. as it applies to claims 1-2, 5, 8, 10, 12, 14, 17 has already been discussed above. However, the reference does not teach such fusion proteins comprising the CBD isolated from *T.reesei*.

Linder et al. teach CBD of *T.reesei*. The reference teaches that the *T.reesei* CBD exhibits reversible binding to crystalline cellulose, can be eluted from cellulose by simple dilution and that the binding is temperature sensitive with an increased affinity at lower temperatures.

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With the teachings of the above references in hand it would have been obvious to one of ordinary skill in the art to use the CBD taught by Linder et al. in place of the CBD taught by Shoseyov et al. to make a fusion protein comprising *T.reesei* CBD linked to an antibody of interest. With a fusion protein comprising a CBD ---which is capable of binding to a cellulose matrix and whose binding can be easily manipulated by just change of temperature—linked to an antibody through an amino acid linker, as taught by Shoseyov et al. it would have been obvious to one of ordinary skill in the art to make a similar fusion protein for affinity purification of a benefit agent such as protein or a peptide wherein the antibody is directed to said protein or peptide. One of ordinary skill in the art would have been motivated to do so as Linder et al. teach that the binding reaction of *T.reesei* CBD to crystalline cellulose is reversible which property can be made use of in elution of fusion proteins bound to cellulose matrix during affinity purification procedure. One of ordinary skill in the art would have been further motivated to use the *T.reesei* CBD as the above reference further teaches that the binding is reversible and temperature sensitive which makes it easier to set the conditions for binding and elution. One of ordinary skill in the art would have a reasonable expectation of success since Shoseyov et al. teach a method of making fusion protein comprising a CBD and Linder et al. teach the CBD from *T.reesei*.

Therefore, the above invention would have been *prima facie* obvious to one of ordinary skill in the art.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Conclusion

None of the claims are in condition for allowance. In the amendment filed on 6-20-03, applicants have provided arguments that were persuasive to overcome the rejection under 35 U.S.C. 112, 1st paragraph. Examiner has withdrawn previous rejections made under 35 U.S.C. 112, 1st and 2nd paragraphs based on the claim amendments and applicants arguments.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao whose telephone number is 703-306-5681. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0196.


MANJUNATH RAO
PATENT EXAMINER

Manjunath N. Rao, Ph.D.
August 29, 2003